K000498

MAR 13 2000

Special 510(k) Summary Statement

I. General Information

Submitter: Coherent Medical Group
2400 Condensa Street
Santa Clara, California 95051-0901
USA

Contact Person: Edward C. Yu
Senior Regulatory Affairs Associate

Summary Preparation Date: February 4, 2000

II. Names

Device Name: Coherent LaserLink Z-1000 Slit Lamp Laser Delivery Adapter

Primary Classification Name: Surgical Laser Delivery Device/Laser Powered Surgical Instrument (Accessory For)

III. Predicate Devices

- Coherent LaserLink Z Slit Lamp Laser Delivery Adapter (K991258) (legally marketed unmodified device)
- Nidek MC-7000 Photocoagulator (K974732)
- Coherent LDS-20 Laser Delivery System (K862568)

IV. Product Description

The device that is subject to this Special 510(k) Premarket Notification is the Coherent LaserLink Z-1000 Slit Lamp Laser Delivery Adapter. The LaserLink Z-1000 is designed to adapt the compatible laser system with appropriate eye safety filter to slit lamps that are not originally designed for laser delivery.

V. Indications For Use

The intended use of the Coherent LaserLink Z-1000 Slit Lamp Laser Delivery Adapter remains the same as originally stated in the Coherent Medical Group 510(k) K991258 cleared by the FDA on May 13, 1999. The intended use is restated below:

This delivery system is indicated for a variety of surgical uses including, but not limited to, the indications specified in your laser operator manual. This device may be used in the medical specialties or procedures for which the compatible laser has received regulatory clearance. Refer to the laser operator manual, Indications for Use section.

VI. Rationale for Substantial Equivalence

The Coherent LaserLink Z-1000 Slit Lamp Laser Delivery Adapter shares the same indications for use, similar design features, and functional features and are therefore substantially equivalent to the legally marketed predicate devices.

VII. Safety and Effectiveness Information

The specifications and intended uses of the Coherent LaserLink Z-1000 Slit Lamp Laser Delivery Adapter are the same or similar to that for the claimed predicate devices. There have been no significant changes or modifications from the predicate devices that affect the safety or effectiveness of the LaserLink Z-1000.

VIII. Conclusion

The Coherent LaserLink Z-1000 Slit Lamp Laser Delivery Adapter was found to be substantially equivalent to similar currently marketed and predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 2000

Mr. Edward C. Yu
Senior Regulatory Affairs Associate
Coherent Medical Group
2400 Condensa Street
Santa Clara, California 95051

Re: K000498
Trade Name: Coherent LaserLinkZ-1000 Slit Lamp Laser Delivery System
Regulatory Class: II
Product Code: GEX
Dated: February 14, 2000
Received: February 15, 2000

Dear Mr. Yu:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K000498

Device Name: Coherent LaserLink Z-1000 Slit Lamp Laser Delivery System

Indications for Use: This delivery system is indicated for a variety of ophthalmic uses including, but not limited to, the indications specified in your laser operator manual. This device may be used in the medical specialties or procedures for which the compatible laser has received regulatory clearance. Refer to the laser operator manual, Indications for Use section.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000498

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)